Gastric Alimetry™

Instructions for Use & Technical Documentation

Body Surface Gastric Mapping System

Gastric Alimetry™ Instructions for Use
IFU-003 Version 11 - April 2026

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CAUTION: Read all warnings, cautions and instructions provided before use.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Rx Only

Table of Contents

1. Description

This manual provides the information necessary to operate the Gastric Alimetry™ System in a safe and effective manner. **Please read and understand this manual before operating the system**.

Gastric Alimetry™ is a medical device and system for performing body surface gastric mapping to provide data on gastric function

The Gastric Alimetry™ System consists of the following components (refer also to diagrams in *Section 4. Device Diagrams*):

- **Alimetry™ Reader:** Acquires and digitizes gastric electrical data. Measures electrical activity from the stomach. Physically connects to the Array and worn by the patient during the test.
- **Gastric Alimetry™ Array (Accessory):** A single-use adhesive patch containing 66 electrodes for recording gastric electrical data. Each individual array package includes an Array Template to aid marking for array placement.
- **Gastric Alimetry™ App:** Designed for use with an iPad mini®, and used for device setup, patient symptom tracking, and data transfers. The Tablet is locked to the Gastric Alimetry™ App.
- **Gastric Alimetry™ Report:** Provided to the physician through the Alimetry™ Cloud after the completion of a test. Reports gastric electrophysiology data together with patient-reported symptoms, and technical information on the quality of the test.
- **Gastric Alimetry™ Dock (Accessory):** A base for charging, storing, and setting up the Reader. Each Gastric Alimetry™ Dock box includes a dock and power adapter/s.

In addition, use of the Gastric Alimetry™ system requires a skin prep gel such as NuPrep®, a measuring tape in cm, a skin marker, and a standardized meal. These components are not supplied with the system.

Gastric Alimetry™ is performed in a clinical setting by medical professionals. The patient arrives fasted of both liquids and solids for at least six hours, usually having ceased any medications that may interfere with gastric motility. The study technician connects the Reader and Array together on the Dock, and registers the patient's data into the Gastric Alimetry™ App. The patient's abdomen is carefully prepared, and the assembled device is attached to the skin overlying the stomach.

Step by step instructions are provided in *Section 8. User Guide*. The patient must remain still during the test, being seated in a reclining chair. The patient logs their symptoms into the Gastric Alimetry™ App at the beginning of the test, then at minimum 15-minute intervals until the test is completed. A fasted baseline recording is performed for the first 30 minutes. The patient is then given 10 minutes to complete a standardized meal, followed by a further post-prandial recording typically for 4-hours. The total test duration including setup is usually 5 hours.

At the end of the test, the data acquired by the Reader and App are uploaded to the Alimetry Cloud™. The Gastric Alimetry™ Report is automatically generated using proprietary algorithms, and is returned to a designated physician via an online portal for review. The report includes data on gastric electrical function and symptoms.

- **WARNING:** Do not use before reading and understanding this manual. System setup and data interpretation should only be performed by trained personnel.
- **WARNING:** Do not operate the Gastric Alimetry™ System for purposes other than intended in this manual.
- **WARNING:** California residents please be advised of the following, pursuant to Proposition 65: This product contains chemicals known to the State of California to cause cancer, birth defect and other reproductive harm.
- **CAUTION:** The safety and effectiveness of Gastric Alimetry™ has not been established in children less than 12 years old.

2. Intended Use / Indications for Use

The Gastric Alimetry™ System is intended to record, store, view and process gastric myoelectrical activity as an aid in the diagnosis of various gastric disorders.

The Gastric Alimetry System is indicated for patients 12 years and older.

3. Contraindications

- Do not use the System on patients that have been diagnosed with, or are suspected to have, life-threatening conditions that could result in immediate danger.
- Do not use the System on patients who have an inability to remain in a relaxed reclined position for the test duration.
- Do not apply the Array over open wounds, abrasions, infected or inflamed areas.
- Do not use the System on patients with very fragile skin who are easily prone to skin tears. Removing the Array could contribute to skin damage in vulnerable patients.

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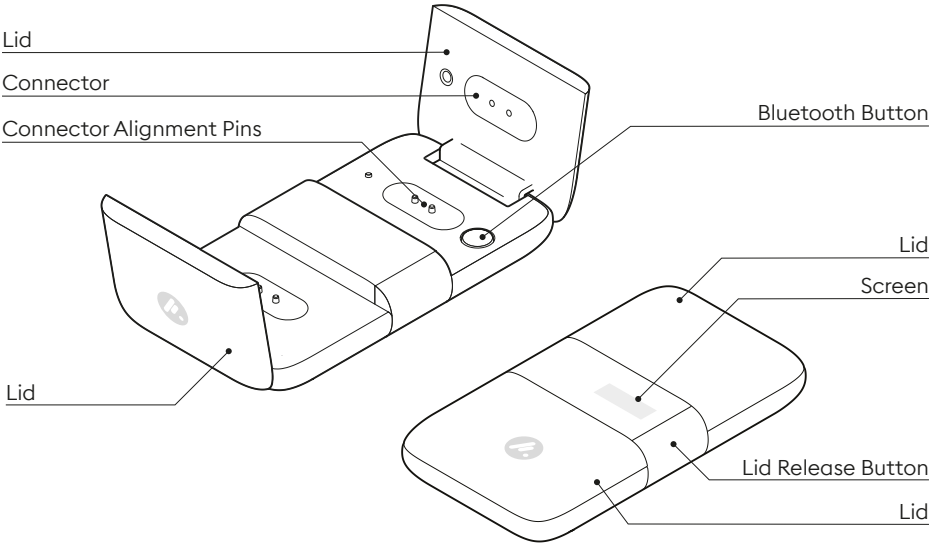
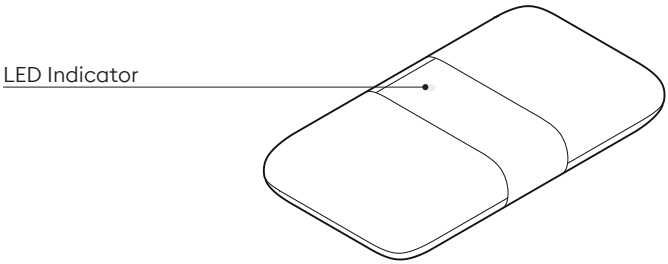
4. Device Diagrams

Reader (Skin Side Facing Up)

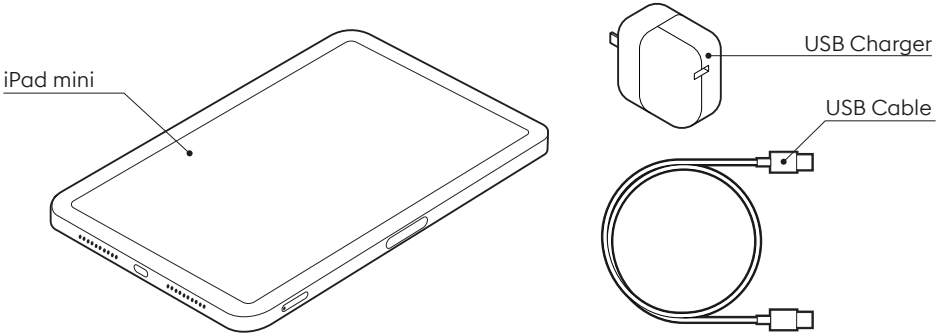


Reader (Skin Side Facing Down)

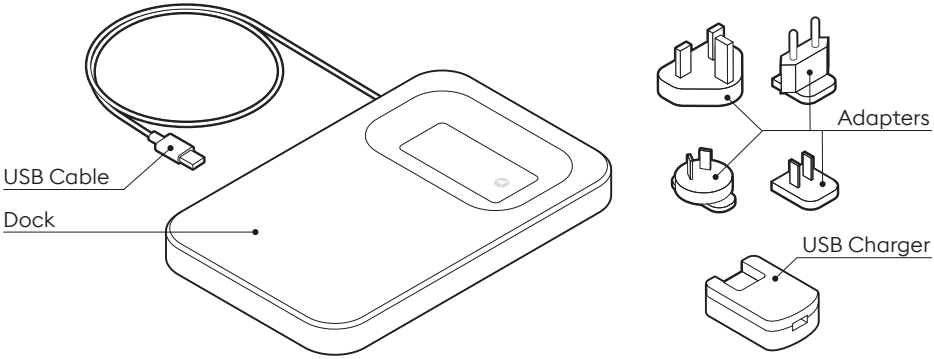


Tablet and Charger

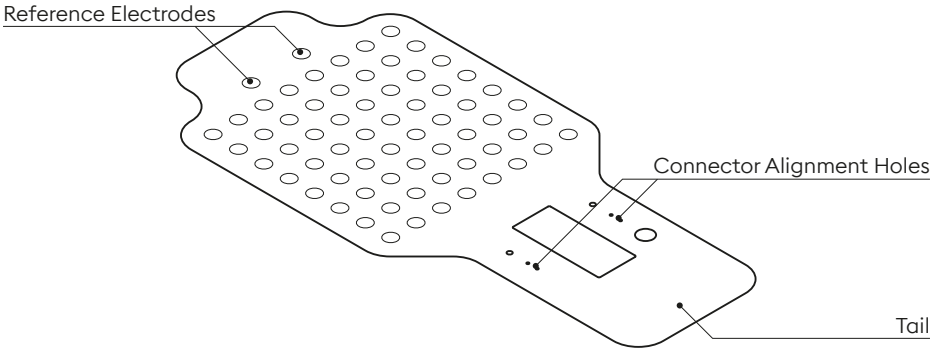
The system is designed for use with an iPad mini®



Dock



Array



5. Reader Interface

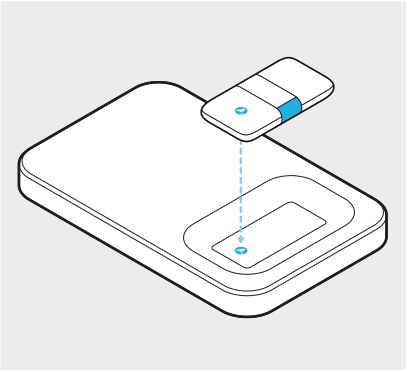
Function	Screen
Initializing	Flashing
Reader Charging	40% Flashing
Reader Charged	100%
Low Battery	Flashing
Error Detected	5043 Flashing
Unique Device Code	AL57* Flashing
Unique Device Code when Connected	AL57*
Array not Connected	Flashing
Array Connected	
Data Syncing with Tablet	Pulsing Side-to-side

**Example Unique Device Code*

Function	LED
On	
On and currently recording	Slow Flashing
Battery Low or Array Error	Flashing

6. Charging

- **WARNING:** Protect the System from contact with liquids. Water damage may cause failure.
- **WARNING**: Use only the charger supplied or a power supply compatible with Dock Specifications. Failure to use compatible accessories may cause the system to perform improperly or cause injury.
- **WARNING**: Do not place any foreign objects on the Dock. Metal or magnetic objects may overheat resulting in damage or burns.
- **CAUTION:** Do not operate with damaged screen, cords or plugs. If damaged, contact Alimetry™ at support@alimetry.com.



- Place the Dock on a stable surface.
- Assemble the power supply by sliding the adapter into the mains charger.
- The Reader is charged by placing it into the recessed area in the Dock (Note: Reader's screen and logo should face up when placed on the Dock). Ensure that the device alignment and orientation are correct with the logo on the Reader being above the logo on the Dock as illustrated adjacent.
- During successful charging, a battery indicator will appear on the display screen of the Reader, indicating charging progress (See *Section 5. Reader Interface*). Fully charging the Reader takes approximately 5 hrs. Full charge will be indicated on the Reader screen (See *Section 5. Reader Interface*).

- Ensure that the Reader is adequately charged prior to starting a Gastric Alimetry™ test. A minimum charge of 83% is needed to complete a standard test. A system check is performed during setup, and setup will not proceed unless there is sufficient charge remaining on the Reader to complete a test.
- Upon completion of charging, the Reader will display 100% charge then enter a sleep mode. The current Reader battery level can be verified by turning on the device using the bluetooth button.
- It is recommended to charge the Reader to a minimum of 60% prior to storage of the device.
- The Tablet is charged by connecting it with its own charging device. Refer to the Tablet instructions for further details. A minimum charge of 50% is needed to complete a standard test. The system check performed during setup assesses the Tablet charge, and setup will not proceed unless there is sufficient charge remaining to complete a standard test.

7. Account Setup

To enable use of the System, an account for the Alimetry Cloud™ will be created by Alimetry and assigned to your practice. User accounts will also be created for each member of the medical staff at your practice who will be performing Gastric Alimetry™ tests or accessing test results.

User Accounts

The practice administrator can add or delete a user within the Alimetry cloud.

User accounts can be created as either Practice User or Practice Admin. Both account types can run tests and access reports, while Admins are also able to create/delete users and delete patient data.

Within the cloud complete the following steps: go to 'users -> create user' to add users and 'users -> delete' to delete users

- **NOTE:** Please be careful when deleting patient users and data. This action will permanently remove the data, including from any backups, after 30 days.

If an audit trial is required for any user account please contact support@alimetry.com

Accessing Alimetry Cloud™

When your user account is created, you will receive an email with details on how to log in and set your password. After your account is configured, you can use your Alimetry Cloud™ username and password to log into the Gastric Alimetry™ App or to access your patients' Reports at https://reports.alimetry.com.

- **NOTE:** User accounts are personal. Each user should only use their own account.

If you are unable to access the App or Reports, please contact support@alimetry.com

Multifactor authentication is required to log into the Alimetry Cloud™, and is enabled by a One Time Password (OTP) sent via email. Additional options include OTP via SMS or through a supported authenticator App. To access these options, log into the Cloud and select 'settings' under the user options at the top right of the screen, and navigate to the 'Security' tab.

8. User Guide

Prior to Use

If you have a hospital-supplied tablet, confirm with your IT department that steps 1–3 have been completed before proceeding.

The IT department should refer to IFU-018 MDM Product Technical Manual (PTM) for tablet set-up instructions.

1. **Turn on and set up the tablet**
   Power on and follow the on-screen prompts to choose your language and country.

2. **Set a passcode**
   Create a passcode to secure the tablet. You can update this anytime in Settings → Touch ID & Passcode.

3. **Connect to Wi-Fi and update**
   Join your secure Wi-Fi network. The tablet will automatically configure itself for the Gastric Alimetry System (this may take a few minutes). Check for and install any available iOS updates while you wait.

4. **Turn on Guided Access**
   Go to Settings → Accessibility → Guided Access → Passcode Settings and set a Guided Access passcode. Using the same passcode as your tablet keeps things simple. Check Section 11 of your manual to confirm the settings are correct.

5. **Charge the Reader**
   Plug the Dock into a power source, place the Reader on the Dock, and confirm it is charging.

6. **Open the app**
   Tap the Alimetry icon on the home screen to launch the Gastric Alimetry app.

Setting Up The System

- Cleaning and disinfection should be completed according to *Section 9. Cleaning and Disinfection.*
- Users should clean their hands thoroughly prior to setting up the Gastric Alimetry™ System.
- The Reader and Tablet should be charged prior to each use.

Prior Patient Preparation

- Patients should fast (no food or drink, including water, tea, coffee, or other beverages) for at least 6 hours prior to the test.
- The following medications should be withheld for at least 2 days prior to testing. Withholding medication should be managed by the treating physician.

- Agents affecting gastric emptying or GI motility (e.g., metoclopramide, prucalopride, tegaserod, erythromycin, domperidone).
- Antispasmodics and strongly anticholinergic medications.
- Opioids (e.g., codeine, morphine, oxycodone, pethidine), sedatives, and tranquilizers.
- GLP-1 agonists can affect test results. The clinician should use their discretion as to the timing for withholding of GLP-1 agents, and/or considering a more prolonged fasting period prior to testing to ensure the stomach is empty.

- Laxatives should not be taken the day before or during the test.
- Regular medications may be taken on the day of the test with a small sip of water only.
- Patients with diabetes should talk to their doctor about how to manage their medicines during the fasting and testing periods.
- Ask patients to refrain from using tanning lotion products prior to the test and 10 days afterwards.
- Ask patients to remove navel piercings prior to the test.

System Setup

Encourage patients to visit the bathroom prior to setting up the System. Patients may also visit the bathroom during the test if required.

System Setup is performed using the Gastric Alimetry™ App. The App is designed to run on an iPad mini® that is provided with the System. Turn on the Tablet and enter the passcode. The App is accessed from the Alimetry™ icon (below).

Enter a valid account name and password to access the App (refer *Section 7. Account Setup*).

If the App has existing tests stored that have not yet been uploaded, it is recommended to upload those tests prior to proceeding. Follow the on-screen instructions to upload existing data. If 5 existing tests are already stored on the App, then further tests cannot be performed until an upload is performed.

System setup proceeds through six steps, as indicated by the App during use. When a step is completed, it is replaced by a check mark in the App interface.

Step	Icon
Device Setup	
Array Setup	
Patient Details	
Measurement	
Skin Prep	
Array Placement	
Signal Check	

Patient Consent

Consenting the patient for data collection: In order to enable Alimetry to collect, use, hold and process data containing personal information in accordance with the Terms laid out in the Gastric Alimetry App, all necessary consents shall be obtained from the patient prior to initiation of the test. If the patient is a minor or not otherwise able to give consent on their own behalf, obtain consent from the patient's parent, legal guardian or another person who is able to give consent on their behalf.

Reader Setup

- **WARNING:** Dropping the Reader may cause damage. Always inspect the Reader enclosure before use, before and after cleaning and disinfection for signs of damage such as cracks, chips, abrasions, or leaks. To avoid the risk of electrical hazards, do not use the Reader if there is any sign of damage. Use of damaged equipment or accessories may cause the system to perform improperly and/or result in injury to the user.
- **WARNING:** MRI Unsafe. Do not use the System in or near to an MRI machine. Use within an MRI machine could result in projectile injury or thermal burns.

Connect the Reader to the Tablet via Bluetooth® by following the App instructions. First, push the Bluetooth button on the Reader. The same 4-digit code will appear on both the Reader Screen and in the Gastric Alimetry™ App. Select 'Connect' in the App to start the connection, ensuring that the code on the iPad matches the code showing on the Reader

When you connect to the Reader for the first time, the Tablet will ask you to pair with the Reader by typing in the 6-digit code displayed on the Reader.

Select a test protocol. Meal options are listed including a standard meal, diabetic meal, gluten-free meal, vegan meal or other. The recommended standard meal is detailed in the Patient Testing: Meal section. As well as the standard test protocol detailed below, users can also enter custom protocols, specifying the fasting duration, meal duration, and postprandial duration. The Reader's recording time life when fully charged is approximately 5.5 hours.

Standard test protocol:

Gastric Alimetry™: 4.5 hours
Fasting duration: 30 minutes
Postprandial duration: 4 hours
Meal duration: 10 minutes

Custom protocols (such as variation in time or meals) can be used, although may not be validated for this test.

Array Setup

- **WARNING:** Do not use the System in patients with allergic reactions to skin adhesives or hydrogels. This could lead to skin irritation.
- **WARNING:** If the Array causes severe discomfort, itching or redness during use, remove Array and stop the test. Skin reactions may occur in rare cases.
- **CAUTION:** Discard product if the Array packaging is damaged. Air leakage into packaging could degrade Array performance leading to data loss and inadequate signal quality.
- **CAUTION:** The Array has a shelf life as specified on the unit packaging. Check prior to opening. Use of an expired Array could lead to data loss and inadequate signal quality.
- **CAUTION:** Remove any naval (belly button) piercings prior to Array placement.
- **CAUTION:** Skin hyperpigmentation may occur at the site of Array placement. This effect is typically temporary but may persist in some individuals.

Open the Array pouch, by tearing across the location tabs indicated on the packaging, which holds the electrode Array and a separate transparent Array Template. Place the Array Template aside - this will be used during the Skin Prep step. Follow the instructions in the App to connect the Array to the Reader. With the blue side of the Array facing upwards, and the adhesive cover still on, carefully place it onto the Reader. Ensure that the connector alignment pins of the Reader are accurately positioned through the corresponding alignment holes on the Array. Setup will proceed only when a correct connection is detected. Do not remove the Array adhesive liner yet.

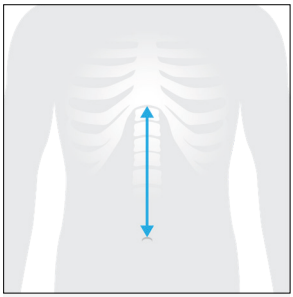
Patient Details

- **CAUTION:** Gastric Alimetry™ is not recommended for patients with BMI >35 kg/m^2. Data quality has not been validated when BMI is >35 kg/m^2.
- **CAUTION:** Ensure patient details are correct and enter them accurately. Improper registration of patients could lead to data loss or clinical errors.

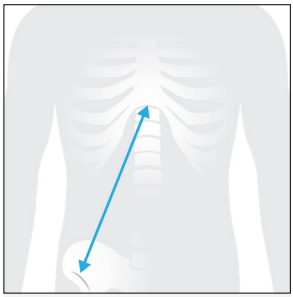
Patient details including the Responsible Physician, name, clinical ID, date of birth, sex, height and weight must be entered into the App per the on-screen instructions.

Measurement

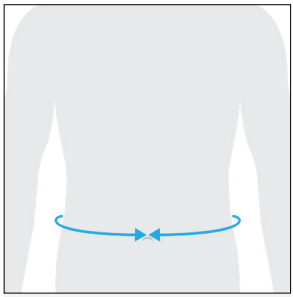
Patient measurements allow correct positioning of the Array. Measurements should be taken accurately with the patient in a supine position and logged into the App. The following measurements are required:



1. Xiphoid to Umbilicus



2. Xiphoid to ASIS

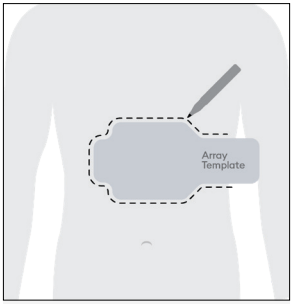


3. Circumference

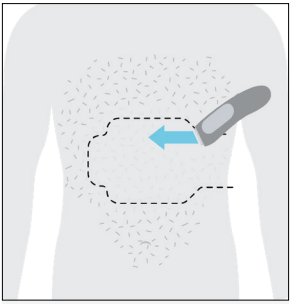
Skin Prep

- **WARNING:** follow the skin prep gel instructions for correct use. Incorrect use can lead to skin irritation and injury.
- **WARNING:** Do not use inappropriate agents for skin preparation. Using inappropriate agents can lead to skin irritation and injury and could adversely affect signal quality.
- **CAUTION:** Patient skin preparation and Array positioning must be performed meticulously. Improper attention to skin preparation and Array positioning steps will lead to missing test data and may require the test to be repeated.

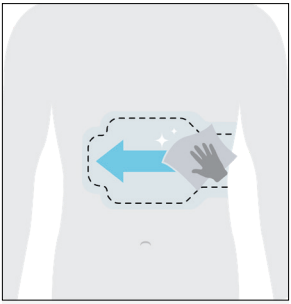
The skin prep Setup step involves marking the correct area that the Array will be placed, shaving this area if necessary, applying the skin prep gel, and drying it off the skin.



1. Mark



2. Shave



3. Clean

After the Measurement step, the Gastric Alimetry™ App will display the correct location for the Array to be placed on the patient, in cm above or below the center of their umbilicus. Measure and mark this point on the patient's midline using a skin marking pen. An outline is then traced onto the patient, with the aid of the Template provided in the Array packaging. Hold the Template against the patient, with the tail of the template toward the patient's left side, the vertical line on the Template aligned with the patient's midline (umbilicus and xiphisternum), and the bottom of the Template at the point already marked on the patient's midline as provided by the App above. The Template is now in the correct position. Trace the edges using the skin marking pen. The Array Template should now be discarded.

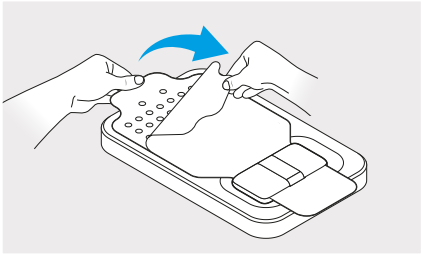
Shave any hair within the marked area using surgical clippers to avoid pain on Array removal, and remove the clipped hair. The skin in the marked area should then be prepped using an appropriate skin prep gel such as NuPrep®. Prepare a cotton swab with a thumbnail size amount of gel, and rub it into the patient's skin in circular motions. This step will exfoliate the skin and improve conductivity. Avoid being too aggressive, but ensure you cover the entire marked area at least 3 times. Use additional skin prep gel and pads as needed.

Wipe all gel residue off the skin with a clean cotton pad.

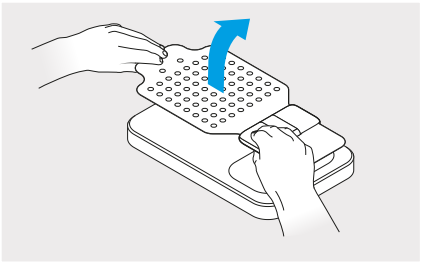
The skin must be dry for the Array to adhere. It is normal for the patient's skin to become red from the exfoliation, but they should not be in pain. Redness typically fades within 48 hours.

Device Placement

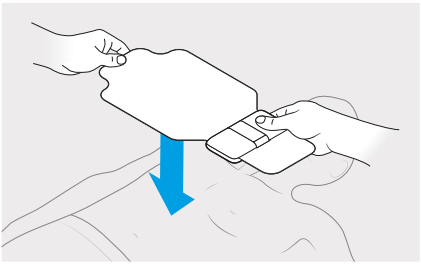
Remove the adhesive backing and place the assembled device (Reader and Array together) on the patient as shown in the following sequence:



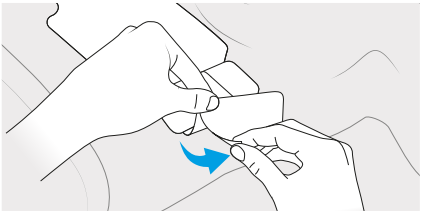
- First, the adhesive cover over the electrodes should be removed. Using your spare hand to stabilize the Array, begin removing the adhesive cover. Pull gently, starting from the outer most edge and moving inwards towards the Reader.



- Once this cover is removed the assembled device is ready to be transferred to the patient. Pick the device up by placing one hand on the Reader and the alternate hand on the outer Array tab. Make sure to hold the Array taut as you move the assembled device so that the Array does not fold onto itself.



- Next, with the patient lying supine, align the Array accurately within the markings on the body and stick it down. The device is on the patient's left side.
- **NOTE:** Do not place the Array over a patient's breast or bra. Instead move the whole Array position downwards, keeping it in the same horizontal alignment, so that it is positioned beneath or under the breast



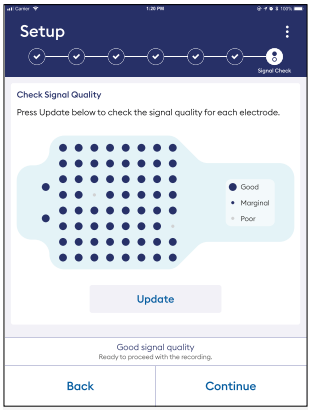
- The second adhesive cover can then be removed from the Array tail. Lift from the innermost edge and pull the cover outwards away from the Reader. Place the tail of the Array on the body to secure the Reader in place.

Measure the distance from the bottom of the Array to the umbilicus and enter the result in the App.

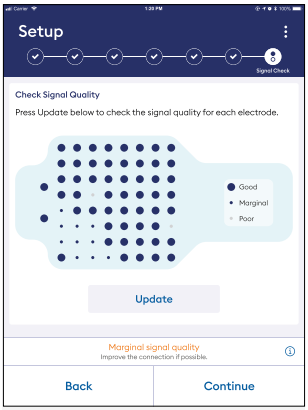
Signal Check

- **WARNING:** If the Reader seems unusually hot, produces an odor or smoke, or leaks, stop use immediately. Contact Alimetry™ at support@alimetry.com.

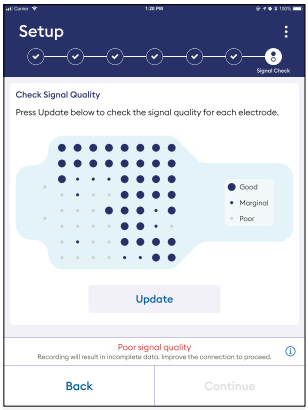
A signal check is performed for each electrode. If 'Good Signal Quality' is reported, continue the test. If 'Marginal Signal Quality' is reported, then improve the connection if possible using the instructions provided in the App then continue the test. If 'Poor signal quality' is reported, the test will not proceed until the problem is resolved; follow the App instructions.



Good Signal Quality



Marginal Signal Quality



Poor Signal Quality

Patient Positioning

During testing, the patient must be positioned in a reclined seating position in a comfortable chair. Relaxing back in a reclining chair will allow the abdominal muscles to fully relax. Contraction of abdominal wall muscles from sitting in a bed or upright position could lead to movement artifacts.

Once the patient has been moved to their chair for the test, press Update on the Check Signal Quality screen in the application to ensure signal quality remains acceptable.

Setup Complete

Once Setup has been completed, an instruction will be provided to hand the Tablet over to the patient. You must enable Guided Access Mode first. This prevents the patient from turning off the screen or exiting the App during the test. To enter Guided Access Mode, click the button at the top right of the iPad three times quickly. You must set a passcode for Guided Access Mode. It is recommended that you use the same passcode that is used for logging into the Tablet.

Patient Testing: Before the Meal

When you first hand the Tablet over to the patient, the App will ask the patient to check that their details are correct and review a data privacy and sharing agreement.

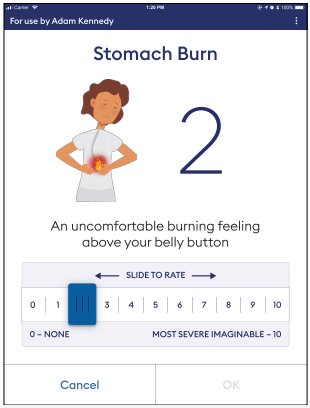
If the patient is at least 18 years old, they are asked to complete a gut-brain wellbeing survey.

Provide the patient with the following instructions:

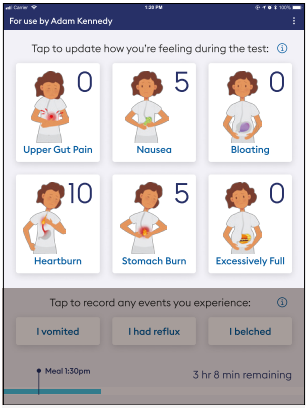
- Do not touch the Array or Reader
- Limit movement during the test
- Avoid talking or laughing
- Do not sleep during the test

The patient uses the App to log their gastric symptoms during the test, including Upper Gut Pain, Nausea, Bloating, Heartburn, Stomach Burn, Vomiting, Reflux, Belching and Excessively Full. After the meal, an additional symptom is captured: Early Satiation (feeling full too quickly). Pictograms and symptom descriptions are provided to support standardized reporting.

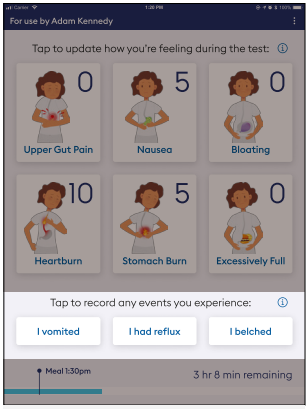
Instruct the patient on how to use the App as follows:



Symptom Input



Dashboard Display: Symptoms



Dashboard Display: Events

- Use the Symptom Input screens in the App to rate the severity of your symptoms on a scale from 0 (None) to 10 (Most Severe Symptom Imaginable).
- During the test, you can update your symptoms at any time using the Dashboard screen. Notifications will occur every 15 minutes to remind you to keep your symptoms up to date.
- You should also log any symptom events that occur during the test (Vomiting, Reflux and Belching) using the buttons on the Dashboard.
- **NOTE:** Observe the patient logging their current symptoms in the App to ensure that they can read and understand the instructions in the App.

Patient Testing: Meal

- **WARNING:** Always inquire about food allergies. The standard test meal bar may include nuts or other contents that could lead to severe allergic reactions. Always provide the correct test meal to the patient.

After 30 minutes, the patients will be instructed to consume the test meal. Provide the correct meal to the patient at this time. An alert will sound in the App. Click “start meal” to begin a countdown timer. You will also have to enter the passcode for the App, so the patient can not start the process themselves.

The meal can also be manually started by selecting the three-dot menu located at the top right of the screen, and selecting **Start Meal.**

The recommended standard meal consists of both a nutrient drink and bar with the following compositions. When choosing a meal, consider the patient's dietary and allergy restrictions.

Nutrient Drink, approximately:
200-330 mL
180 - 240 kCal
Carbohydrate 14-33 g, Protein 8-20 g, Fat 4-9 g, Fiber 2-5 g

Nutrient Bar, approximately:
68-76 g
230-260 kCal
Carbohydrate 23-45 g, Protein 9-20 g, Fat 5-8 g, Fiber 4-7 g

Patients will have 10 minutes to complete the test meal. Encourage the patient to eat as much of the meal as possible to best provoke symptoms.

When they are finished eating, they should click “I’m done with my meal” to proceed with the test.

Patient Testing: After the Meal

After the meal, patients are asked to report what % of the meal they were able to complete, and to rate whether they experienced Early Satiation (Fullness).

The test continues for 4 hours after the meal to evaluate gastric function over a typical gastric emptying duration.

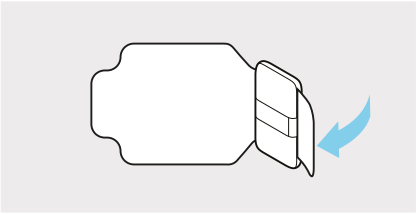
Patients should continue to update their symptoms at least every 15 minutes, and log events that occur. They should try to limit movements during this time, but can take comfort breaks as required during the test. A test completion bar on the bottom of the App Dashboard shows the patient how much of the test is remaining.

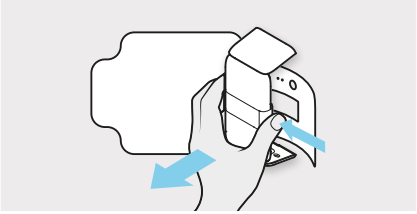
After Testing

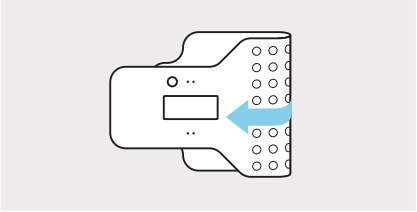
Once the test is completed, an alert will sound in the App. Re-enter the passcode for the tablet, which will open the Data Upload page. Prompts on the App will show when the data is being transferred from the Reader to the App, and then from the App to the Cloud.

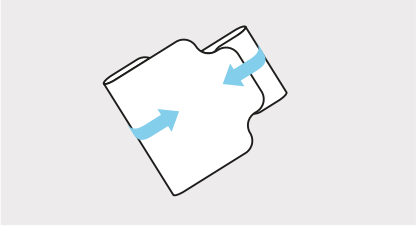
End Guided Access Mode again, by clicking the home button at the bottom of the tablet three times quickly. You will again be asked for a passcode. Then you may Log Out by accessing the menu on the top right corner of the App.

Remove the Reader and Array from the patient's body as shown in the sequence below.









- It is recommended to use an Adhesive Remover wipe when removing the Array from the patient.
- **WARNING:** Remove the array gently. Rapid removal of the Array from the patient can cause skin injury.
- First, the tail of the Array should be removed by gently peeling it away from the skin, i.e. starting on the patient's left side. Array removal is aided by providing gentle supporting counter-traction on the patient's skin with the alternate hand.
- When the Reader is free from the body, detach it from the Array by pressing the lid release button. Once released, close the lids to the Reader again to protect the internal surfaces, and return it to the Dock for subsequent cleaning.
- Next, gently remove the remainder of the Array from the patient's body.
- The Array is a single-use disposable device and it should be discarded after use. Fold the Array in half as shown to hide the adhesive surface, and discard it into a standard clinical waste container.
- **WARNING:** Do not reuse the array. It is a single use disposable product. Re-use could lead to poor signal quality. Cross-contamination could lead to patient infection.

9. Cleaning and Disinfection

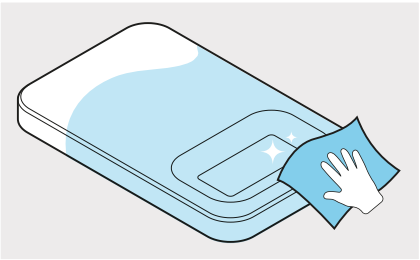
- **WARNING:** Do not use the System on a patient without thorough cleaning and disinfection of the Reader, Dock and Tablet. Cross-contamination could lead to patient infection
- **WARNING:** Leave all surfaces visibly wet for 5 minutes as part of disinfection. Failing to complete 5 minutes contact time could result in cross contamination.
- **CAUTION**: Disinfectant wipes residues can cause skin irritation. Use IPA to remove wipe residues at the end of disinfection.
- **CAUTION:** Only clean and disinfect the components with approved cleaning wipes. Improper cleaning or disinfection methods or using non-approved cleaning and disinfecting solutions may damage equipment or lead to inadequate cleaning or disinfection.

The Dock, Reader and Tablet shall be cleaned and disinfected with wipes containing quaternary ammonium and isopropanol as active ingredients, such as CaviWipes™ or similar. The Dock, Reader and Tablet do not withstand an automated cleaning process and should only be cleaned manually.

Ammonium wipes	**Alcohol wipes**	**Gloves**
		
CaviWipes™ or Similar	*70% Isopropyl Alcohol Wipes*	*Nitrile Gloves*

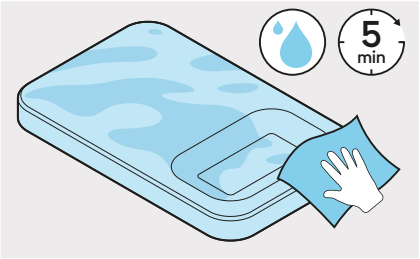
Dock

Step 1: Clean



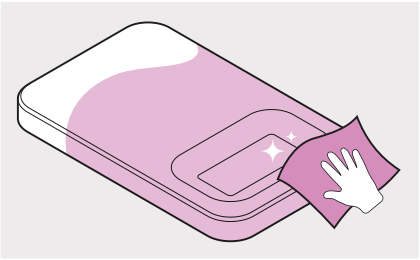
- Use a fresh ammonium wipe and gloves.
- Wipe down the top surfaces of the Dock until visibly clean.
- Change the wipes as necessary.

Step 2: Disinfect



- After cleaning you must disinfect the Dock using a fresh ammonium wipe.
- Periodically wipe the same surfaces and make sure the Dock remains **visibly wet for a minimum of five (5) continuous minutes**. Use additional fresh wipes as needed.

Step 3: Wipe Off Residues

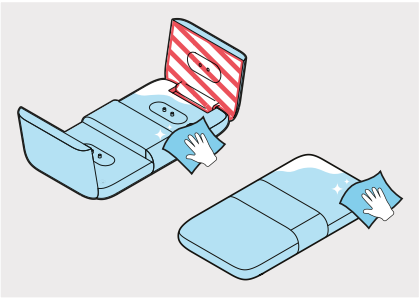


- Now use a fresh 70% isopropyl alcohol (IPA) wipe.
- Wipe the same surfaces to remove residual disinfection detergent.
- Allow surfaces to air dry.

Reader

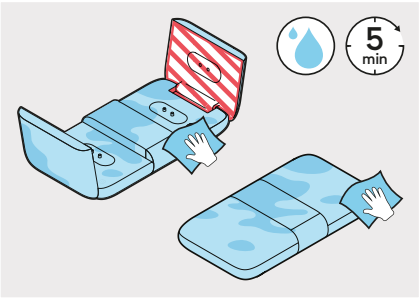
- **CAUTION:** Do not touch, clean or disinfect the connectors inside the Reader lids. Exposing them to cleaning fluids or rubbing them with cleaning cloths may cause damage.
- **CAUTION:** Do not touch the connector. Touching the connector can damage the contacts, resulting in limited or inconclusive results.

Step 1: Clean



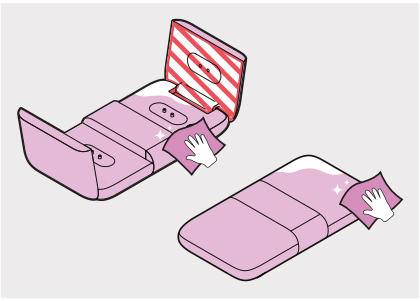
- Use a fresh ammonium wipe and gloves. Clean the inside of the Reader first **EXCEPT** for the surfaces of the lids containing the connectors.
- Close the lids. Clean the external surfaces of the Reader until visibly clean.
- Change the wipes as necessary until visibly clean.

Step 2: Disinfect



- After cleaning you must disinfect the Reader using a fresh ammonium wipe.
- Periodically wipe the same surfaces and make sure the Reader remains **visibly wet for a minimum of five (5) continuous minutes.** Use additional fresh wipes as needed.

Step 3: Wipe Off Residues



- Now use a fresh 70% isopropyl alcohol (IPA) wipe.
- Wipe the same surfaces to remove residual disinfection detergent.
- Allow surfaces to air dry.

Tablet

The Tablet is cleaned and disinfected in a similar manner to the Dock and Reader.

- **NOTE:** Avoid moisture entering the charging port of the Tablet.

- Once clean and disinfected, visually inspect the Reader, Dock and Tablet for signs of damage or wear.
- Dispose of cleaning and disinfection material in accordance with all applicable regulations.

10. Reports

Gastric Alimetry™ Reports are generated automatically after each test on the Alimetry Cloud™. Reports will usually be made available within 24 hrs of completion of the test. Reports are generated in PDF format and are available via your secure login at https://reports.alimetry.com (for details, see Section 7 Accessing Alimetry Cloud™ above). Patients can be located in the Alimetry Cloud™ by their name or ID as was entered into the Gastric Alimetry™ App during test setup. Once the correct patient is identified, click the "Report.pdf" link to download and view the Report. A Supplementary Report containing data from all 64 channels from the Gastric Alimetry™ Array is also available in the Alimetry Cloud™.

If the patient details were entered incorrectly in the App, contact support@alimetry.com to update the patient's details in the Report.

If you have difficulty finding or accessing Reports on the Alimetry Cloud™, please contact Alimetry™ at support@alimetry.com.

Interpretation of Test Data

- **CAUTION:** Exercise diligence in the interpretation of the Gastric Alimetry System study results.
- **CAUTION:** Excessive movement of the patient during test may impact results. Exercise clinical judgment in the interpretation of data obtained during excessive movements.
- **CAUTION:** Amplitude data have not been validated for clinical use.

The Report should only be interpreted by an appropriately qualified medical specialist. Please refer to the 'Report Interpretation Guide' (IFU-010) for detailed instructions on how to read and interpret test data.

Gastric Alimetry is intended to be used as an adjunct to other diagnostic methods as part of a comprehensive evaluation of patients with symptoms consistent with gastrointestinal motility disorders.

11. Software Updates

The firmware on the Reader must be up to date in order to perform a Gastric Alimetry™ body surface gastric mapping test. Firmware updates will be automatically triggered on connecting to the Reader during setup and should be activated prior to proceeding with setup.

The Tablet and App software should be up to date when performing a test. Alimetry will contact users when an App update is available with instructions on how to update the App. iPadOS should be updated to the latest version by the user as soon as it is available.

To activate Guided Access mode open the Gastric Alimetry App and triple-click the Power (Top) button.

To configure the guided access settings or ensure the guided access settings have been correctly configured:

1. Open the Gastric Alimetry App
2. Activate Guided Access mode by triple-clicking the Power (Top) button.
3. Triple-click the Power button again and enter the passcode.
4. Tap the Session Settings button at the bottom left corner
5. The following should be toggled OFF :
    - Top Button
    - Volume Buttons
6. Tap Resume (top-right corner) to exit Guided Access and confirm that pressing the top power button and volume buttons has no effect

The new liquid glass experience on iPadOS 26 causes a significant delay when the App requests that you enter a passcode such that the passcode entry appears unresponsive for a period of 1-2 seconds after which the passcode can be entered. You can prevent this delay by reducing the liquid glass transparency effect in iOS settings:

1. Open the Settings App and click on Accessibility on the left hand menu
2. Click Display & Text Size on the right hand menu
3. Turn ON Reduce Transparency on the right hand menu

Alimetry uses semantic versioning for software updates (i.e. Major.Minor.Patch). The App and Firmware version can be found by navigating to the iPad 'Settings' and searching 'Alimetry'. Only the App uses a build number included in brackets after the version, e.g. 3.3.0(1), where (1) is the build number. The Report and Algorithm version are included in the Reference section of the Report.

12. Troubleshooting and FAQs

Issues Arising During Device Setup

App Login is not working or is 'locked'.

Ensure that the user has a correctly registered name and password by contacting your local institutional administrator. If an incorrect password is entered 5 times, the system will lock out the user for 15 minutes. Further incorrect passwords will lead to further lockouts. Please contact support@alimetry.com if assistance is required.

Local internet access is interrupted.

A functioning internet connection is not required to log in or to conduct a Gastric Alimetry™ test. However, the user will not be able to upload the test data to generate a Report until an internet connection is re-established. A maximum of 5 completed tests will be stored on the App. Users are unable to perform further tests if 5 completed tests remain to be uploaded.

Bluetooth won't connect.

Ensure that the Reader is charged and within close range of the Tablet. Check that Bluetooth is enabled on the tablet by going to 'Settings' → 'Bluetooth'. Remove any previously paired Readers by pressing the information button (ⓘ) and selecting "Forget This Device". Repeat pairing by following the Setup instructions in the App. An individual Bluetooth code will appear on the Reader screen as well as in the 'Available Devices' in the App Setup screen. If the Reader fails to appear on the Available Devices list despite being fully charged and in close range, a reset of the Reader can be performed. This is achieved by holding down the Bluetooth button on the Reader for longer than 20 seconds. Then restart setup.

The patient has a specific food allergy, intolerance, or dietary requirement.

Patient dietary allergies, intolerances and restrictions should always be checked prior to device setup. Recommended brands provided for the standard test meal bar and drink are vegetarian and lactose-free. Diabetic, gluten-free and vegan meal options are provided in the App. Non-standard dietary options have not been validated and may lead to variances in test outcomes. Please check individual meal and drink product brands for cultural dietary information.

The Reader appears to have a mechanical fault or an Error is appearing on the display screen.

Please contact support@alimetry.com and do not perform further tests until the issue is resolved.

The Array won't connect to the Reader.

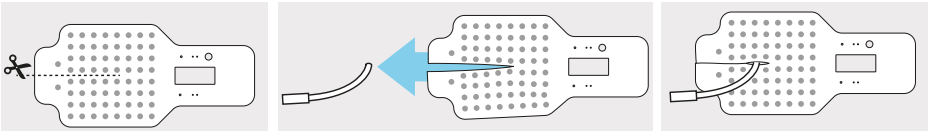
Check that the Reader is sufficiently charged. Ensure that the connector alignment pins of the Array are correctly aligned over the pins on the Reader, and that the Array is sitting flat in the mounting area with the blue side facing upwards. The Bluetooth button of the Reader should be visible through the matching hole in the Array. Ensure that the tablet is located near to the Reader and repeat the Connect Array step in the Gastric Alimetry™ App. If problems persist, contact Alimetry™ at support@alimetry.com

The suggested Array position is over a patient's breast.

Do not place the Array over a patient's breast or bra. Instead move the whole Array position downwards, keeping it in the same horizontal alignment, so that it is positioned beneath and/or under the breast.

The patient has a gastric feeding tube.

If the patient has a gastric feeding tube, the Array can be carefully cut to allow accurate placement around the tube. Use sharp scissors to carefully cut the middle of the Array, ensuring you do not cut any silver traces. Then position the Array snugly around the feeding tube in the position shown below, instead of using the Placement instructions provided in the App Setup. Keep the Array clear of any damaged skin.



The patient has had previous gastric surgery.

If the patient has had previous gastric surgery, this should be factored into the interpretation of the test by the responsible physician. Gastric resections may modify test results.

Signal Quality is reported as 'Marginal' or 'Poor' during Setup.

Signal quality is determined by measuring the impedance at every electrode in the Array, and requires correct skin preparation and Array placement. If marginal or poor signal quality is reported during Setup, refer to the information button (ⓘ) on the relevant App screen for instructions on how to resolve the issue.

1. Improve contact with the skin by pressing down over the electrodes with poor signal quality. **Acceptable contact is confirmed when the reference electrodes** have at least marginal signal quality, and the **Continue** button can be pressed.

2. If pressing down does not help, gently lift the flap that contains the **reference electrodes** and re-prep that area. Then secure the flap to maintain contact throughout the test.

3. **If contact remains 'Poor' and the Continue button remains grey**, remove the Array, re-prep the skin, and restart the setup with a new Array.

Issues Arising During Patient Use

The Patient missed notifications for symptom logging.

Patients should log symptoms at least every 15 minutes as per the notification schedule in the App, in order to ensure symptom data is accurate. Overlooking a small number of notifications to log symptoms is acceptable as long as an overall symptom profile is captured sufficiently accurately during the test. The Gastric Alimetry™ Report includes information on the frequency of patient symptom logging for evaluation by the referring physician.

An 'event' happened multiple times within a 15 minute interval.

Patients should attempt to log frequently recurring 'events' (i.e. vomiting, reflux and belching) as often as possible. If events occur too frequently to log every occurrence, patients should make efforts to capture an appropriately representative symptom experience.

The Reader dislodged from the patient during a recording.

The Array is a single-use product, and failure of the adhesive is very unlikely with correct use. Attempt to reattach the Array and Reader. If repeat dislodgement occurs, review the setup instructions and attempt to repeat the test with a new Array, while also ensuring that patients are not touching the Reader during the test. If problems persist, please contact support@alimetry.com.

Can the patient go to the bathroom during a test?

Yes. Patient movements should be restricted as much as reasonably possible during the test period, and it is best to advise patients to visit the bathroom before a test. However, a small number of brief comfort breaks will not critically affect data quality. Patient movement is monitored by an accelerometer in the Reader and is included in the Gastric Alimetry™ Report.

The Reader was dropped.

The Reader is a complex electronic medical device and should be treated with care. While the Reader has been designed to withstand minor falls, dropping the Reader from a height or onto hard flooring may result in damage. If Reader damage or a fault is observed after a drop, please report to support@alimetry.com.

The Reader or Tablet ran out of charge.

A system check occurs during device setup, and if insufficient charge is found, the test may not proceed until the Reader and Tablet are charged. This check makes it unlikely that the Reader or Tablet will run out of charge during a test. In the unlikely event that Reader charge failure occurs during a test, abort the test and report this event to support@alimetry.com.

Can the patient be left unattended through the study?

Yes. Once the test is successfully in progress, patients may be left unattended within a safe clinical environment. However, it is advisable to intermittently check on patient progress, comfort, movement and symptom-logging compliance to ensure test quality is satisfactory. Note that patients will also need access to their meal at the designated time.

The patient refused or was unable to eat the meal.

The App encourages patients to complete as much of the meal as possible. Failure to eat a meal may compromise correct interpretation of the data. If a meal is not eaten or is only partially eaten, it is advisable to proceed with completing the Gastric Alimetry™ test. Meal completion data is included in the Report, and can be evaluated by the responsible physician.

The meal time does not start automatically at the expected time

The meal can be manually started by selecting the three-dot menu located at the top right of the screen, and selecting Start Meal. You will have to enter the passcode for the App, to avoid the patient being able to start the process themselves.

The patient or physician needs to stop the test before it is completed.

A test can be aborted at any time by accessing the menu on the top right corner of the App. Incomplete tests will be reported, but may be insufficient to provide reliable test data. This will be interpreted by the responsible physician. Repeat the test if required.

The patient reports severe itchiness or discomfort during the test.

The Gastric Alimetry™ test is usually very well tolerated, however, a small degree of itch or discomfort may arise during testing. Patients should be reassured that this is normal. In rare circumstances, patients may have severe allergies to the Array adhesive. If severe itchiness or discomfort occurs during a test, the Array should be removed and the test stopped, with appropriate medical treatment sought if required. Serious adverse events should be reported to support@alimetry.com

Can the device be used in conjunction with an MRI or CT scanner?

Use within or near to an MRI scanner is dangerous; please refer to Warnings above. Using the device within a CT scanner will lead to excessive artifacts.

Issues Arising After Patient Use

The patient has a skin reaction.

Skin reactions can occur to the skin preparation gel, adhesive, or hydrogels. Symptoms can include redness, discomfort and itch. These symptoms are usually mild and self-limiting, and can be treated by applying a soothing skin cream. It is common for the skin to remain red for up to 72 hrs after a test. If the itch persists, or if there is swelling or other concern, advise the patient to consult a medical professional. An anti-histamine or other treament may be required as indicated. Please report significant adverse events to feedback@alimetry.com.

The report has not become available.

Reports are generally available within 24 hrs of performing a test. If a report is not available, ensure that the test data was uploaded from the Reader, by logging in to the tablet used in the test via the Gastric Alimetry™ App and connecting to the Reader. An automatic check is performed at login for tests that have not yet been uploaded. Ensure that internet access is available to complete test upload. If further assistance is required, or if a Report cannot be accessed, please contact support@alimetry.com.

The Reader fails to charge.

Ensure correct alignment between the Reader and Dock as described above, and ensure that the Dock is securely connected to an active power socket. Charging will be confirmed by the progress indicator on the Reader display. In case of charging failure despite correct alignment, contact support@alimetry.com.

I forgot the Guided Access Mode Passcode.

It is recommended that you use the same passcode that is used for logging into the Tablet. If you forget the Guided Access passcode while it is enabled, you can reset the Tablet once the test is finished with the following steps: 1) press and quickly release the Volume Up button, 2) press and quickly release the Volume Down button, and 3) press and hold the Sleep/Wake button until it restarts. Once it restarts you can reset the Guided Access passcode in the Tablet settings, by going to 'Settings' → 'Accessibility' → 'Passcode Settings' → 'Set Guided Access Passcode'.

13. Maintenance and Service

- **WARNING:** Do not modify or disassemble the device. Accessing internal electronic parts could cause component failure or injury. In case of device failure, return the product to Alimetry™ by contacting support@alimetry.com.
- **CAUTION:** Service must be performed by authorized Alimetry™ personnel only.
- **CAUTION:** There are no user-serviceable parts. Do not open Reader's enclosure, remove parts or attempt repair.

Alimetry™ performs remote diagnostics on Readers. If maintenance of a Reader is required, the nominated institutional administrator will be contacted by our support team.

14. Privacy and Cybersecurity Statements

Alimetry™ maintains strict patient confidentiality through industry-standard cybersecurity practices. The Gastric Alimetry App communicates with the Alimetry Cloud via a TLS 1.2 connection. Please ensure that the App is connected to a secure WI-FI network within your medical practice and that the software is up to date when performing a test (see Section 11).

When accessing the Alimetry Cloud, please consider the following browser options:

- Google Chrome 55 or higher
- Mozilla Firefox 50 or higher
- Apple Safari 10 or higher
- Microsoft Edge 15 or higher
- Internet Explorer 11

To modify patient information that was incorrectly entered in the App or to delete patient data, contact Alimetry at support@alimetry.com.

Please contact alimetry@support.com if a cybersecurity event is detected or suspected.

15. System Specifications

Reader Specifications (Model: AL001-A)

Dimensions:	6.8 x 12.7 x 1.9 cm
Weight:	200 g
Medical equipment type:	BF applied part
Service life:	3 Years
Power:	1 Lithium-polymer battery (rechargeable)
Battery life (typical):	5.5 Hours recording time
Battery service life:	300 Cycles
Shelf life (battery not charged):	1 Year
Charging:	Wireless
Protection:	Over-voltage protection, over-current protection
Number of channels:	64
Sampling frequency:	250 Hz
Measurement units:	Volt
Accuracy:	±1% at 1000 µV
Range:	Up to 1000 µV
Resolution:	0.5 µV
Frequency range:	DC to 0.5 Hz
Mode of use:	Continuous
Short-range RF transmit/receive:	2.4 GHz Bluetooth low energy, effective radiated power < 1 mW
Frequency band of transmission:	2.4 GHz
Bandwidth of receiver:	2.360 - 2.500 GHz
Type and frequency of modulation:	2-Mbps GFSK

Dock Specifications (Model: AD001)

Dimensions:	20.7 x 32.6 x 2.8 cm
Weight:	830 g
Wireless charging standard:	QI
Wireless charging power:	5W
IP classification:	IP22

Dock Power Supply (Generic):

Input:	100-240V; 50/60Hz
Output:	DC 5V / 2A
Input interface:	USB Type A
Electrical safety:	Complies with electrical safety (e.g. IEC 62368-1, IEC 60950-1) or equivalent local regulations.
EMC safety:	Complies with EMC safety (e.g., IEC 61204-3, FCC Part 15 Class B, EN55032, EN55024) or equivalent local regulations.

Array Specifications (Model: AS001-1)

Dimensions:	18 x 38.6 cm
Weight:	25 g
Number of electrodes:	66
Adhesive type:	Acrylate
Electrode material:	Silver/silver chloride
Electrode gel:	Hydrogel
Shelf life:	3 Years
Service life:	Single-use consumable
	The array does not contain latex.

Tablet Specifications

The device is designed for use with a 6th or 7th Generation iPad mini®. Refer to the iPad mini® instructions for use for relevant device specifications.

Environmental Operating Conditions

The permissible environmental conditions for use of the Gastric Alimetry™ System are:

Reader temperature:	+10°C to +40°C
Reader humidity:	10% to 90% (non-condensing)
Reader atmospheric pressure:	700 to 1060 hPa
Array temperature:	+10°C to +40°C
Array humidity:	10% to 90% (non-condensing)
Array atmospheric pressure:	700 to 1060 hPa
Dock temperature:	+10°C to +40°C
Dock humidity:	10% to 90% (non-condensing)
Dock atmospheric pressure:	700 to 1060 hPa

Transport and Storage Conditions

- **WARNING:** Store only within the range of environmental conditions specified in the technical specifications.
- **CAUTION:** Storage and transport of the Array beyond the recommended temperature and humidity levels could lead to degradation of device performance.
- **CAUTION:** Protect the Reader and Dock from direct sunlight.

Reader transport temperature:	-20°C to +70°C
Reader storage temperature: (up to 1 year)	-20°C to +35°C
Reader transport and storage humidity:	10% to 90% (non-condensing)
Array transport temperature:	-20°C to +70°C
Array storage temperature:	+5°C to +30°C
Array transport and storage humidity:	10% to 90% (non-condensing)
Dock transport and storage temperature:	-20°C to +70°C
Dock transport and storage humidity:	10% to 90% (non-condensing)

System Performance

The Gastric Alimetry™ System records and transmits electrophysiological signals from the stomach for analysis after receipt of the data. Movement artifacts and other noise may affect signals. Refer to the Gastric Alimetry™ Report Interpretation Guide for further information.

In the event it cannot record or transmit data, either the Reader will notify the user of an error or the report will indicate the data is incomplete.

16. Electrical Safety and EMC

Reader and Dock

The Gastric Alimetry™ System is intended to acquire gastric electrophysiological data for analysis by qualified and trained healthcare professionals. Electromagnetic fields, however, can cause distortion or degradation of this information, affecting this performance.

The Gastric Alimetry™ has been designed for use within electromagnetic environments specified in Tables in this section. To avoid radiated and conducted electromagnetic disturbances, the customer or the user of the Gastric Alimetry™ System should assure that it is used within these stated specifications.

- **WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- **WARNING:** No modification of the Gastric Alimetry™ System equipment is allowed.
- **WARNING:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- **WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Gastric Alimetry™ System, otherwise, degradation of the performance of this equipment could result.

Electromagnetic Emissions

The Gastric Alimetry™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the Gastric Alimetry™ System should assure that it is used in such an environment.

- **NOTE:** The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11 EN55011	Group 1	The Gastric Alimetry™ System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 EN55011	Class A	The Gastric Alimetry™ System is suitable for use in all establishments, except domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN/IEC 61000-3-2	Not applicable	Not applicable
Voltage fluctuations/ flicker emissions EN/IEC 61000-3-3	Not applicable	Not applicable

Electromagnetic Immunity

The Gastric Alimetry™ System is intended for use in the electromagnetic environment specified below. The customer or the user of the Gastric Alimetry™ System should assure that it is used in such an environment

Immunity test	EN/IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) EN/IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical transients/bursts EN/IEC 61000-4-4	Not applicable. This Reader does not function on AC power.	Not applicable.	Main power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m@50Hz or 60Hz 3 orthogonal orientations	30 A/m 50 and 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.4 GHz 28 V/m 385, 450, 810, 870, 930 MHz 18 Hz pulse 9 V/m 710, 745, 780 MHz 217 Hz pulse 28 V/m 1720, 1845, 1970, 2450 MHz 217 Hz pulse 9 V/m 5240, 5500, 5783 MHz 217 Hz pulse	3 V/m 80 MHz to 2.4 GHz 28 V/m 385, 450, 810, 870, 930 MHz 18 Hz pulse 9 V/m 710, 745, 780 MHz 217 Hz pulse 28 V/m 1720, 1845, 1970, 2450 MHz 217 Hz pulse 9 V/m 5240, 5500, 5783 MHz 217 Hz pulse	Portable and mobile RF communications equipment should be used no closer to any part of the Gastric Alimetry™ System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Equations and key recommended separation distances are shown in Recommended Separation Distances section below. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

- **WARNING:** Do not expose the System to strong electromagnetic fields or sources of static electricity. Do not place the device on top of other electrical equipment.
- **WARNING:** The Gastric Alimetry™ System may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSIONS requirements.
- **WARNING:** Avoid concurrent use of the Alimetry Reader together with electrocautery devices. Electrocautery devices can cause electromagnetic interference.
- **WARNING:** Do not use systems with radio frequency identification (RFID) technology in the vicinity of the Gastric Alimetry system. Electromagnetic interference from RFID systems may cause a degradation in the performance of Gastric Alimetry system, leading to patient injury or impairment.
- **CAUTION:** Portable and mobile RF communications equipment can affect medical electrical equipment.
- **CAUTION:** The Gastric Alimetry™ System needs special precautions regarding EMC and needs to be utilized according to the EMC information provided in the following tables.

Immunity test	EN/IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
	30 kHz CW @ 8 A/m	30 kHz CW @ 8 A/m	
Proximity Magnetic Fields IEC 61000-4-30	134.2 kHz, 2.1 kHz PM @ 65 A/m	134.2 kHz, 2.1 kHz PM @ 65 A/m	The EUT was placed on a non-conductive table an dradiating coil placed at 50mm from the EUT.
	13.56 MHz, 50 kHz PM @ 7.5 A/m	13.56 MHz, 50 kHz PM @ 7.5 A/m	

[a] *Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Gastric Alimetry™ System is used exceeds the applicable RF compliance level above, the Gastric Alimetry™ System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Gastric Alimetry™ System.*

[b] *Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.*

- **NOTE:** At 80 MHz and 800 MHz, the higher frequency range applies.
- **NOTE:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Devices such as cellular/mobile phones, radio transmitters, and transceivers transmit radio waves (RF), which can create disturbances. The Gastric Alimetry™ System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

If radiated and conducted electromagnetic disturbances are observed and performance is affected, the user or customer should take measures to mitigate, including relocation or reorientation of the system.

Recommended Separation Distances

The Gastric Alimetry™ System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Gastric Alimetry™ System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Gastric Alimetry™ System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (P, in watts)	**Separation distance according to frequency of transmitter (d in meters)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	80 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

- **NOTE:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- **NOTE:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

This Gastric Alimetry™ System complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This system may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

The Reader has been tested and meets FCC RF exposure guidelines when used and operated for its intended purpose and as instructed in the manual.

For body worn operation, this Gastric Alimetry™ System has been tested and meets FCC RF exposure guidelines when used and positioned with the Gastric Alimetry™ Array. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

Tablet

- **WARNING:** The Tablet emits electromagnetic radiation which can affect other medical equipment within its vicinity. Use the Tablet in accordance with your healthcare facility's mobile device use policy.

The device is designed for use with an iPad mini®. Refer to the iPad mini® instructions for relevant information.

17. Device Disposal

- **CAUTION:** At the end of its life, the Reader including its battery must be disposed of in accordance with local laws and regulations concerning electrical and electronic equipment.

The Reader and the Dock are included in the scope of the directive 2002/96/EEC on Waste Electrical and Electronic Equipment (WEEE) and of the national decree(s), which transpose provisions of such directive. At the end of their lifetime, these devices cannot be disposed of as unsorted municipal waste. They may contain materials that pose a risk to the environment if proper disposal procedures are not followed. Prior to disposal, items should be clean and contaminant free. The Reader and the Dock must be collected separately at specifically authorized treatment facilities. For recycling assistance, please contact support@alimetry.com.

Information about the collection and disposal of Waste Electrical and Electronic Equipment (WEEE) can be found at the following website: www.alimetry.com/recycling.

18. Symbols Glossary

	Manufacturer	This symbol shall be accompanied by the name and address of the manufacturer (i.e. the person placing the medical device on the market), adjacent to the symbol.
	Date of manufacture	This symbol shall be accompanied by a date to indicate the date of manufacture. This shall be expressed as in ISO 8601 as four digits for the year and, where appropriate, two digits for the month and two digits for the day. The date shall be located adjacent to the symbol.
	Use-by date	This symbol shall be accompanied by a date to indicate that the medical device should not be used after the end of the year, month or day shown. The date shall be expressed as in ISO 8601 as four digits for the year and, where appropriate, two digits for the month and two digits for the day. The date shall be located adjacent to the symbol.
	Batch code	This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol.
	Catalogue number	The manufacturer's catalogue number shall be adjacent to the symbol.
	Serial number	This symbol shall be accompanied by the manufacturer's serial number. The serial number shall be adjacent to the symbol.
	Medical Device	
	Rx Only	United States Federal law restricts medical devices to sale by or on the order of a licensed healthcare practitioner.
	Keep away from sunlight	
	Keep dry	
	Temperature limit	The upper and lower limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.

	Humidity limit	The humidity limitation shall be indicated adjacent to the upper and lower horizontal lines.
	Atmospheric Pressure limit	The atmospheric pressure limitations shall be indicated adjacent to the upper and lower horizontal lines.
	Do not re-use	
	Do not use if package is damaged	
	Consult instructions for use	
	Caution	
	Separate collection	
	Type BF applied part	
	Magnetic resonance (MR) unsafe	
IP22	Degrees of protection provided by enclosure	

19. Intellectual Property

Alimetry™ products are protected by copyrights, registered designs, trademarks and patents, and all original images, text and designs on our material are the property of Alimetry Ltd. Refer to www.alimetry.com for further information.

Product names mentioned in this manual may be trademarks of their respective owners. iPad® and iPad mini® are trademarks of Apple Inc., registered in the U.S. and other countries. NuPrep® is a trademark of Weaver and Company, registered in the U.S. and other countries.

20. Warranty Statement

Alimetry warrants that the Gastric Alimetry system (excluding consumable items), when used in accordance with the instructions for use, shall be free from defects in workmanship and materials and will perform in accordance with Alimetry's official published product specifications for a period of 1 year from the date of purchase by the end user.

This warranty does not cover damage caused by:

- accident
- misuse or abuse
- modification
- failure to follow instructions for use
- unsuitable physical or operating environment
- failure caused by a product not supplied or manufactured by Alimetry
- other defects not related to materials or workmanship

Warranty claims can only be made when accompanied by proof of purchase (ie., sales receipt).

If this warranty applies to a defective product, Alimetry will, to the extent permitted by law, at its option, repair or replace the product or the defective material or part. If Alimetry repairs or replaces any product, the warranty period for any product repaired or replaced does not extend beyond the original warranty period.

21. Contact Details

For orders, assistance or report faults, unexpected operation or events, please contact the local representative.

Online Assistance	www.alimetry.com support@alimetry.com
New Zealand	Alimetry Ltd 86 Symonds St, Auckland 1010, New Zealand

- **NOTE:** Any serious incident that has occurred in relation to the device should be reported to Alimetry, the local authority, and if required the local responsible representative.